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EXAMINER	
ORWIG, KEVIN S	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,242	KAMIYAMA ET AL.	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 11-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 11-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Apr. 2, 2009 are acknowledged and have been fully considered. Claims 8-10 are cancelled; claims 1, 2, and 5 are amended; claims 11-27 have been added. Claims 1-7 and 11-27 are now pending.

OBJECTIONS/REJECTIONS WITHDRAWN

The objection to the specification (i.e. the priority claim on the first line and the abstract) is withdrawn, in light of the amendments to the specification and abstract.

The rejection of claims 1-7 under 35 U.S.C. 112, 2nd paragraph is withdrawn, in light of the claim amendments.

The rejection of claims 1-7 under 35 U.S.C. 103(a) is withdrawn upon further consideration.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

Claims 1-7 and 11-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-7 are indefinite in the recitation "...the primary amino group and/or carboxyhydrazide group in copolymer B is included at a density of one per 5-100 molecular chains of the (meth)acrylic acid ester comonomer..." in claims 1 and 5. Claims 11-27 are indefinite in

the recitation "...the primary amino group and/or carboxyhydrazide group in copolymer B is included at a density of one per 5-100 molecular chains of the (meth)acrylic acid ester comonomer..." in claims 11 and 13.

Specifically, claims 1, 5, 11, and 13 recite the following two limitations:

A) "...wherein the primary amino group and/or carboxyhydrazide group is present at a density of at least 2 per molecular chain of the copolymer B," and

B) "...the primary amino group and/or carboxyhydrazide group in copolymer B is included at a density of one per 5-100 molecular chains of the (meth)acrylic acid ester comonomer..."

The first of these two limitations (limitation A above) is clear and definite. However, the second of these two limitations (limitation B above) in combination with the first renders the claims indefinite. Both limitations are related to the amount of primary amino group and/or carboxyhydrazide group in copolymer B. However, the limitations can be construed as limiting the amount of the primary amino group and/or carboxyhydrazide group to *different amounts*. For example, the limitation A requires at least two primary amino group and/or carboxyhydrazide groups per molecular chain of copolymer B. Limitation B then requires 1 primary amino group and/or carboxyhydrazide group per 5-100 molecular chains of the (meth)acrylic acid ester comonomer.

It is unclear what is meant by the term "molecular chains of the (meth)acrylic acid ester comonomer". However, this could be construed as meaning a chain of monomers (i.e. a copolymer chain). In this scenario, limitations A and B are incompatible, since

limitation A requires at least two of the recited groups be present in each chain of copolymer B; whereas limitation B requires only one of the recited groups be present per 5-100 molecular chains of monomers (i.e. polymer chains), and thus does not require that each chain have at least two of the recited groups. Thus, one of ordinary skill in the art could reasonably construe "molecular chains of the (meth)acrylic acid ester comonomer" to be a copolymer chain. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of these claims are indefinite.

Claim Rejections - 35 USC § 103 (New)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over TERAHARA (JP 2004-83520; Published Mar. 18, 2004; translation provided) in view of KAMIYAMA (WO 00/44846; Published Aug. 3, 2000; of record) and DELAUNOIT (U.S. 6,617,387; Filed Mar. 17, 1999).

1. Since JP 2004-83520 is in Japanese, a machine translation (provided) is relied upon herein. Page and paragraph numbers refer to the machine translation. Terahara discloses a transdermal patch comprising an adhesive agent which comprises acrylic polymers that have no substantial carboxyl groups (paragraph [0007]-[0008], [0019]; [0023]; claim 1). The adhesive taught by Terahara comprises a crosslinkable acrylic copolymer of polyacrylate and diacetone acrylamide (i.e. copolymer A of instant claim 1) (paragraphs [0013], [0023] and [0024]; claim 5) and a basic nitrogen-containing acrylic copolymer wherein the nitrogen may be a primary amino group (i.e. copolymer B of instant claim 1) (paragraphs [0010], [0011], [0035], and [0036]). Terahara teaches that the acrylic polymer (i.e. copolymer A) comprises (meth)acrylic acid esters as the main

constituents of the acrylic polymer (paragraph [0023]) and teaches that it is preferred to copolymerize these main chain constituents with another monomer, such as diacetone acrylamide (paragraph [0024]; claim 5).

2. Terahara teaches that the ratio of the adhesive base to the nitrogen-containing copolymer (i.e. copolymer B) is from 9:1 to 1:1 and teaches that the nitrogen-containing copolymer is present in a range of 1-30% by weight relative to the total amount of the adhesive base (paragraphs [0010], [0040], [0041], and [0052]). The adhesive base of Terahara includes both the acrylic copolymer and a rubber copolymer which are themselves present in a ratio of 1:1 to 1:9 (paragraph [0031]). Thus, the ranges taught by Terahara encompass the instantly claimed amount of copolymer B. For example, when the adhesive base is composed of a 1:1 mixture (i.e. 100 parts each) of the acrylic and rubber polymers, and the total of these two copolymers (i.e. the adhesive base) is in a ratio of 9:1 with the nitrogen-containing copolymer, the nitrogen-containing copolymer is present at a level of 22.2 parts by weight.

3. Terahara is silent as to the specific diacetone acrylamide content of the acrylic copolymer in their invention, and do not explicitly teach that the nitrogen-containing copolymer contains no free carboxyl groups.

4. However, Terahara teaches that polymers containing carboxyl groups are undesirable for applications to human skin because these types of polymers do not have optimal compatibility with skin and that acrylic polymers containing no substantial carboxyl groups can be used to solve this problem (paragraphs [0007], [0008], [0019], [0023]; claim 1). Terahara further teaches that it is preferable to decrease the carboxyl

group content of the acrylic polymers as much as possible (paragraph [0026]). In light of this teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove the free carboxyl groups from all polymers in the adhesive composition by any means known in the art, to provide a more skin-compatible adhesive as taught by Terahara.

5. Furthermore, Kamiyama discloses a skin-compatible adhesive composition for transdermal patches comprising crosslinked acrylic copolymers (abstract; page 8, 3rd paragraph). Kamiyama teaches that where the adhesive is for use in a transdermal patch, it is preferred that a polar monomer be copolymerized with the alkyl acrylate main constituent component. Diacetone acrylamide is such a preferred polar monomer component because it enables more advantageous drug loading (page 8, last paragraph to page 9, 2nd paragraph). Kamiyama teaches that the polymers should comprise at least 50% by weight of alkyl(meth)acrylates (p. 8, last full paragraph) and teaches that diacetone acrylamide should be present in no more than 50% w/w because higher amounts can lead to reduced adhesion (page 9, 3rd paragraph). Kamiyama also teaches that a particularly preferred embodiment of the adhesive polymer is a combination of two (meth)acrylic acid alkyl esters and diacetone acrylamide in a ratio of 4:4:3 (page 10, 2nd paragraph).

6. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include diacetone acrylamide as an essential component of the acrylic copolymer of Terahara in the range of 3-45% (i.e. as the minor component). It would have been routine for one of ordinary skill in the art to

optimize the levels of diacetone acrylamide in the copolymer, particularly in light of Kamiyama's teaching that levels of the monomer component (e.g. diacetone acrylamide) can be manipulated to provide optimum drug retention and delivery (page 9, 2nd paragraph). Given the preferred polymer taught by Kamiyama (page 10, 2nd paragraph), it would have been obvious to one of ordinary skill in the art at the time of the invention to prepare an adhesive polymer without carboxyl groups and having diacetone acrylamide as an essential component in the range of 3-45%. One would have been motivated to do so because Kamiyama teaches that diacetone acrylamide confers advantageous drug loading and should be present in an amount of 50% or less. Further, it is well within the skill of the ordinary artisan to optimize the levels of diacetone acrylamide as taught by Kamiyama. One would have been motivated to remove the carboxyl groups from the acrylic copolymers included in the adhesive per Terahara's teaching that doing so improves skin compatibility. Therefore if an artisan wanted to produce a skin-compatible adhesive for a transdermal patch with high drug loading capability, one would have been motivated combine Terahara and Kamiyama and claim 1 is rendered obvious over these references.

7. Claims 1-7 are product-by-process type claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." See MPEP § 2113. Claims 1 and 5 are drawn to crosslinkable adhesives comprising two copolymers wherein the crosslinking between the copolymers occurs in a specific way. Thus, the claims do not actually require that the crosslinking take place, only that the polymers be capable of performing the recited reaction. A skilled artisan would know that diacetone acrylamide can be crosslinked with hydrazides and amines (see Delaunoit, col. 4; lines 44-46). The copolymer composition of Terahara is clearly capable of being crosslinked. Thus, the limitation "...the crosslinking of copolymer A by copolymer B occurs as carbonyl groups of the diacetoneacrylamide in copolymer A form covalent bonds by dehydration reaction with the free primary amino groups and/or carboxyhydrazide groups of copolymer B" does not add patentable weight to the claim. Furthermore, claims 2-4 are drawn to the pressure-sensitive adhesive of claim 1 wherein copolymer B is obtained by various reaction schemes. The substance and structure of the claimed pressure sensitive adhesive is not affected by this limitation, which merely reflects processes that could be used to make the adhesive of claim 1. Since the adhesive of claim 1 may comprise *either* a primary amino group *or* a carboxyhydrazide group in copolymer B, the limitation "...copolymer B is an acrylic copolymer obtained by..." does not add patentable weight to the claim. If the product in this claim is the same as or obvious from a *product* of the prior art, the claim is unpatentable. The adhesive of claim 1 is clearly disclosed in the prior art, thus claims 2-4 are rejected as unpatentable over Terahara and Kamiyama.

8. Regarding the newly added claim limitations, an issue of indefiniteness has been noted. See 112 2nd paragraph rejection *supra*. Since the two new limitations regarding the amount of primary amino or carboxyhydrazide groups appear to be incompatible as discussed above, the newly added claim limitations will be construed as requiring at least two primary amino or carboxyhydrazide groups per molecular chain of copolymer B for the purposes of this rejection. In this regard, Terahara teaches that the basic nitrogen-including polymer can include a copolymer of two or more kinds of polymerizable amines (paragraph [0036]). Thus, it would be obvious to an ordinary artisan to include at least two primary amine groups per molecular chain of the basic nitrogen-containing polymer, as Terahara clearly intends.

9. Regarding claim 5, Terahara teaches a patch for transdermal use wherein the adhesive layer is disposed on a base material (i.e. a backing layer), which may be various types of cloth, polymers, or an aluminum sheet (paragraphs [0008], [0019], and [0020]). Thus claims 5 and 7 are rendered obvious over Terahara and Kamiyama.

10. Additionally, Terahara teaches the use of plasticizers in the adhesive of the invention. Terahara teaches that the amount of plasticizer is not particularly limited, but is preferable to be between 5-70% of the compounds in the adhesive layer (paragraphs [0052] and [0053]). Therefore the combination of Terahara and Kamiyama renders claims 1-7 obvious.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA)

1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that Terahara only discloses tertiary amines in the examples of the disclosure (response, p. 11).

Applicants are reminded that the instant rejection was made under U.S.C. 103(a) obviousness and, as stated in the MPEP, "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments," and, "Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004)." The MPEP further states, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use."" See MPEP § 2123 (Subsection II). Terahara clearly teaches that primary amino groups are acceptable for

use in the invention (paragraph [0035).

Moreover, applicants assert that, "If a tertiary amino group-including amine is used in the present invention, as described in Terahara, the crosslinking reaction between copolymer A and copolymer B does not occur." Nothing currently of record demonstrates this to be the case, and applicants have provided no evidence to support this assertion. See MPEP § 716.01(c)(II), "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

Applicants argue that, "It is clear that the intention of Terahara is to provide adhesives that do not involve crosslinking reactions." and refers to (paragraph [0023]) of Terahara to support this assertion (response, p. 12):

> "in this connection, the acrylic polymer including no substantial carboxyl group (carboxylic acid group, -COOH) and hydroxyl group (-OH) in the molecule according to the invention means an acrylic polymer that has no carboxyl group or hydroxyl group in the molecule thereof that may become a functional group upon crosslinking". (emphasis added).

Applicants have misinterpreted Terahara's teachings. Rather than teaching that crosslinking is not intended at paragraph [0023] (reproduced above), Terahara is defining what is meant by "no substantial carboxyl group and hydroxyl group". In the passage referred to, Terahara teaches that these groups should not be present upon crosslinking (i.e. after crosslinking). Thus, in contrast to applicants' assertion, Terahara clearly contemplates crosslinking of the disclosed polymers.

Applicants argue that Terahara does not specifically describe a (meth)acrylic acid copolymer comprising a (meth)acrylic acid alkyl ester as the main constituent

component and diacetoneacrylamide as the minor constituent component (response, p. 12).

Terahara's silence as to the diacetone acrylamide content of the copolymer was acknowledged (see paragraph 3 of the prior Office Action). Kamiyama provides the motivation why one of skill in the art would include diacetone acrylamide as the minor component of the copolymer (see paragraphs 5 and 6 of the prior Office Action). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants argue that examples 1-3 of Terahara contain the basic nitrogen-containing polymer in higher amount than the acrylic polymer (response, p. 12).

Applicants are again reminded that the teachings of Terahara are not limited to the examples of the disclosure. Terahara teaches that the ratio of the adhesive base to the nitrogen-containing copolymer (i.e. copolymer B) is from 9:1 to 1:1 and teaches that the nitrogen-containing copolymer is present in a range of 1-30% by weight relative to the total amount of the adhesive base (paragraphs [0010], [0040], [0041], and [0052]).

Applicants argue that Terahara uses a rubber polymer while the present invention does not (response, p. 12).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the exclusion of a rubber polymer) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants argue that Kamiyama does not provide for a basic-nitrogen containing polymer and that neither Terahara nor Kamiyama disclose the instantly claimed crosslinking reaction (response, p. 12-13). Applicants argue that Kamiyama has certain drawbacks that are inferior to the instant invention (response, p. 13).

Again, applicants are attacking references individually when the rejection was based on a combination of references. Terahara provides for the basic nitrogen-containing polymer. As noted *supra*, the limitation of how the crosslinking reaction occurs is a product-by-process type limitation that is not afforded patentable weight. However, even if, *in arguendo*, this limitation were given weight, the ordinary artisan would have expected such a reaction based on the teachings of Terahara and Delaunoit. Any alleged drawbacks to Kamiyama are not relevant to the instant rejection.

New claims 11-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terahara in view of Kamiyama and Delaunoit.

11. The teachings of Terahara, Kamiyama, and Delaunoit are presented *supra*. Terahara teaches primary amino groups, but does not disclose carboxyhydrazide groups. Kamiyama clearly establishes that free carboxyhydrazines (i.e. not part of the polymer) are useful crosslinking agents for use with acrylate copolymers comprising diacetone acrylamide as a preferable essential substituent (col. 7, lines 11-22).

Kamiyama teaches the use of polyhydrazides (col. 7, lines 21-22). It is noted that instant copolymer B is nothing more than a polyhydrazide. Furthermore, it is well established that changes in the sequence of adding ingredients is *prima facie* obvious. *Ex parte Rubin*, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render *prima facie* obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).

12. Applicants are claiming an adhesive comprising copolymer B, which comprises a (meth)acrylic acid alkyl ester and a carboxyhydrazide group. The prior art (e.g. Kamiyama) clearly establishes that the very same carboxyhydrazides (e.g. adipic acid dihydrazide) are preferred for the very same purpose as instantly claimed. The end result of polymerizing instant copolymers A and B would be a crosslinked copolymer A-copolymer B wherein the two polymer chains are joined by the carboxydihydrazide residue. The only difference between Kamiyama and the instantly claimed polymers is the order in which the carboxyhydrazide is added. In the prior art, it is added simultaneously to the mixture of copolymers A and B. In the instant case, the

carboxyhydrazide is added first to copolymer B, which is then reacted with copolymer A. Absent evidence to the contrary, the net result is the same.

13. Claims 11-27 are product-by-process type claims. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See MPEP § 2113. Claims 11 and 13 are drawn to crosslinkable adhesives comprising two copolymers wherein the crosslinking between the copolymers occurs in a specific way. Thus, the claims do not actually require that the crosslinking take place, only that the polymers be capable of performing the recited reaction. A skilled artisan would know that diacetone acrylamide can be crosslinked with hydrazides and amines (see Delaunoit, col. 4; lines 44-46). The copolymer composition of Terahara is clearly capable of being crosslinked. Thus, the limitation "...the crosslinking of copolymer A by copolymer B occurs as carbonyl groups of the diacetoneacrylamide in copolymer A form covalent bonds by dehydration reaction with the free carboxyhydrazide groups of copolymer B" does not add patentable weight to the claim. Furthermore, claims 12, 17-19, and 24 are drawn to the pressure-sensitive adhesive of claim 1 wherein copolymer B is obtained by various reaction schemes. The substance and structure of the claimed pressure sensitive adhesive is not affected by this limitation, which merely reflects

processes that could be used to make the adhesive of claim 11 or 13. Thus, the limitation "...copolymer B is an acrylic copolymer obtained by..." does not add patentable weight to the claim. If the product in this claim is the same as or obvious from a *product* of the prior art, the claim is unpatentable. The adhesive of claims 11 and 13 is clearly disclosed in the prior art, the claims Terahara, Kamiyama, and Delaunoit.

14. Regarding the limitation that copolymer B is present in an amount of 0.3-20 parts relative to 100 parts of copolymer A, Terahara teaches that the content of the basic nitrogen-including polymer in the adhesive base is not restricted (paragraph [0040]). Terahara teaches that the content of the basic nitrogen-including polymer is preferably 1-30% by weight (paragraph [0041]). Moreover, the weight ratios taught by Terahara are *preferable*, but clearly not limited to these only. Additionally, Terahara teaches that the amount of the basic nitrogen-including polymer influences the skin permeability of included drugs (paragraph [0040]). Thus, the amount of the basic nitrogen-including polymer is clearly a result-effective variable that would be optimized by the skilled artisan.

The other limitations of claims 11-27 were discussed supra with respect to claims 1-7, and the rationale for those claims is applicable to claims 11-27 as well. Claims 11-27 are rendered obvious over Terahara, Kamiyama, and Delaunoit.

Summary/Conclusion

Claims 1-7 and 11-27 are rejected; claims 8-10 are cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611